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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/608,333 | 06/30/2003 | Ramani R. Ranatunge | 102258.153US | 8773 |
| 24395 | 7590 | 02/18/2005 | EXAMINER | |
| WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004 | | | SOLOLA, TAOFIQ A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/608,333 | Applicant(s) RANATUNGE ET AL. | |
| | Examiner Taofiq A. Solola | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 3-13, 17-27, 40-54 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-2, 14-16, 28-39, 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-58 are pending in this application.

Claims 3-13, 17-27, 40-54, 58 are drawn to non-elected invention.

RESTRICTION REQUIREMENT

The election of group II, claims 1-2, 14-16, 28-39, 55-57, with traversal in the paper filed 12/16/04 is hereby acknowledged. The traversal is on the basis that all the inventions are related. This is not persuasive because the inventions are patentably distinct for reasons set forth in the restriction requirement of 11/19/04. Applicant also cited the conditions in *In re Kase*, USPQ2d 1063, in support of Applicant's contention. This is not persuasive because the claims are not proper Markush claims. See below. Applicant further contends that by searching nitrosated and/or nitrosylated cyclooxygenase-2 inhibitor all the inventions could be searched. This is not persuasive because such is not a proper search strategy as individual compound must be searched.

The restriction is still deemed proper and therefore made FINAL.

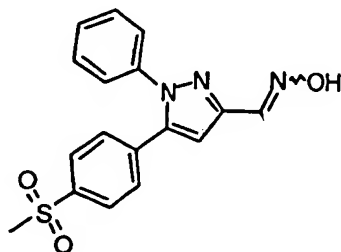
Claims 1-2, 14-16, 28-39, 55-57, are being examined in part subject to the election made by applicant. Applicant elected compound A described at page 107, line 13 to page 110, line 18, of the specification.

Status of Claims

The Office has reviewed the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention encompasses all compounds within the scope of the claims, which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds, which fall in related subclasses. Examination of the elected

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compound AND the entire scope of the invention encompassing the elected compound as defined by common classification results in the following:



In reference to the above formula, sides d and f are double bonds, sides e and g are single bonds in formula II. Also, A-B is N-C and $-X^2-Y^2-Z^2-$ is $=CR^4-CR^5=N-$ in formula II. However, applicant fails to define R^4 and R^5 .

As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 1-2, 14-16, 28-39, 55-57 are withdrawn from further consideration by the Examiner, under 37 CFR § 1.142(b), as being drawn to a non-elected subject matter. The withdrawn compounds are patentably distinct from the elected invention as they differ in structure and element and would require a separate search. In addition, a reference, which anticipates the elected invention would not render obvious the non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 14-16, 28-39, 55-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Substituents R1, R1', R2, R4, and R5 are not defined in the specification. By adding the definitions the rejection would be overcome. However, applicant should note that the introduction of a new matter into the specification would raise the issue of new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-2, 14-16, 28-39, 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Substituents R1, R1', R2, R4, and R5 are not defined in the claims so as to determine the metes and bounds thereof. See the Examiner's suggestion above.

Objection

Claims 1-2, 14-16, 28-39, 55-57 are objected to for containing non-elected subject matter. To place the application in condition for allowance, applicant must amend the claims as set forth above.

Claims 1-2, 14-16, 28-39, 55-57 are improper Markush claims. All the inventions of a proper Markush claim must make a contribution over the art (i.e. they must share a substantial structural feature: a common core that is novel), and the common core must have utility. Once the core is novel, any and/or all substituents of the core are deemed allowable with the core.

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In the instant case, the contribution made by all the compounds is a phenyl ring because everything else is a variable. This is not deemed a contribution by the compounds over the art because the ring is well known in the art. Also, the specification fails to set forth any utility arising from the ring. In addition, the ring is not searchable, as any attempt to search it would run the computer out of memory.

Therefore, the Office, starting with the elected species, developed the phenyl ring to the point of novelty. Applicant is not bound by the Examiner's suggestion, because applicant may submit a structure that is common to all the claimed compounds, which must be novel and have utility to satisfy the requirements of proper Markush claim. Otherwise, applicant must amend the claims as suggested by the Office to put the claims in condition for allowance.

Rejoinder

Claims 40-50 would be rejoined if the diseases recited in the claims are limited to only those having support in the specification by way of biological assay or journal articles. For example, just because the instant compounds can heal ulcer does not imply healing any wound. This is also true for various forms of cancers and bacterial infections. Claim 46 fails to recite specific diseases and therefore may not be rejoined. If the intended disorders in claim 46 are the same as cited in other claims such would be deemed a duplicate.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish at the beginning.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

February 14, 2005